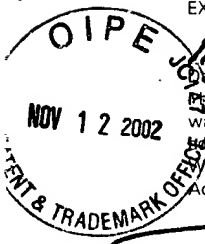


#35/HR  
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EXPRESS MAIL CERTIFICATE



Date 11/12/02 Label No. 208555205-05

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Patent Trademark Office

Docket No: 0632/OD916

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Hsien-Jue CHU

Serial No.: 09/007,385

Art Unit: 1647

Confirmation No.: 4879

Filed: January 15, 1998

Examiner: S. Turner

For: STREPTOCOCCUS EQUI COMPOSITIONS AND METHODS OF USE

DECLARATION UNDER 37 C.F.R. §1.132 OF ROBERT DAILY

Hon. Commissioner of  
Patents and Trademarks  
Washington, DC 20231

Sir:

I, Robert Daily, declare that:

1. I am a citizen of the United States of America and reside at 14008 Bradshaw, Overland Park KS. 66221.

2. I am currently the Director of the Equine Business Unit for Fort Dodge

Serial No. 09/007,385 Docket No. 0632/OD916

Completed  
w/ HKM/ST  
2-25-03

Animal Health.

3. I understand that this patent application has been rejected as being obvious over references related to (1) attenuated *S. equi* vaccine and adjuvant and (2) references describing saponin adjuvants. I also understand that evidence of commercial success in selling this product provides evidence of unobviousness.

4. The *Streptococcus equi*/saponin composition of the present invention provides immunity and protection for intranasally vaccinated horses against the infectious disease, strangles, which is caused by *S. equi*. The attenuated *S. equi*/saponin composition, commercially sold under the trademark Pinnacle™ I.N., comprises live attenuated *Streptococcus equi* and saponin, an immunostimulant having the property of stimulating mucosal immunity. The commercially sold product Pinnacle™ derives its success from its ability to stimulate an effective protective immune response to *Streptococcus equi* in horses by contacting the cells of the nasopharyngeal mucosa, thus helping prevent strangles in horses. The mode of delivery also makes it an attractive alternative to intramuscular vaccine compositions.

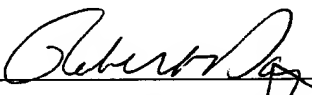
5. The *Streptococcus equi*/saponin composition sold under the trademark Pinnacle™ has achieved significant commercial success since launch of the product in February of 1998. Sales figures of the Pinnacle™ product reflect increases in units sold and unit price over each of the past four years after rapid market saturation in the first year. During the 11 months of 1998, when the product became commercially available, it sold over hundreds of thousands of doses and achieved gross sales in the million dollar range. Over the next 4 years, there has been a steady increase in commercial sales, with gross sales exceeding several millions of dollars (see the graph attached as Exhibit 1). In particular, there was an increase of 45% in the number of doses and an increase of 44% in gross sales from 1998 and 1999. In 2000, the number of doses sold increased 23%, and gross sales increased 30%, over the year before. The number of doses sold in 2001 increased another 5%, while gross sales increased 13% from the year before.

So far in 2002, through September, the total number of doses sold has increased 2.2% and sales have increased 30% over the totals for the first nine months of 2001. Whereas units sold and gross sales of the claimed *Streptococcus equi*/saponin composition have both increased yearly, in the third quarter of 1999 sales of a competitive killed *S. equi* product, produced by Bayer, declined approximately 39% from the prior year. This decrease in sales of the killed vaccine resulted from entry of Pinnacle™ *Streptococcus equi*/saponin product into the commercial market in 1998.

6. These sales data establish that the *Streptococcus equi*/saponin product demonstrated ample commercial success and has had a significant impact in the market. The users of this product are responsible for the health of expensive horses; they would not adopt a product unless it had substantial efficacy. The introduction of Pinnacle™ I.N. provided a safe and effective alternative to traditionally reactive intramuscular strangles vaccines. This product has virtually reinvented the strangles vaccine market. Thus, the increases in sales reflect product superiority. An inferior product, like the killed *S. equi* vaccine, would not achieve the commercial success achieved by the Pinnacle™ product. The Pinnacle™ I.N. product achieved gross sales greater than the killed product in just its *second* year. Furthermore, the advantages of Pinnacle™, which are responsible for its commercial success and its reinventing the strangles vaccine market, result from the attenuated bacterium combined with saponin, i.e., the claimed subject matter of the patent application.

7. I declare further that statements made in this Declaration my own knowledge are true and that all statements made on information and belief are believed to be true and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 11/11/02

  
Robert Daily